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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|------------------|
| 10/619,091 | 07/14/2003 | William R. Schmeling | 19596-0541 (45738-286749) | 8595 |
| 23370 | 7590 | 05/04/2006 | EXAMINER HYUN, PAUL SANG HWA | |
| JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309 | | | ART UNIT 1743 | PAPER NUMBER |

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|-----------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/619,091 | SCHMELING, WILLIAM R. |
| | Examiner | Art Unit |
| | Paul S. Hyun | 1743 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
 - 4a) Of the above claim(s) 2-5 and 9-15 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,6-8 and 16-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 17 December 2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/5/04, 4/29/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a magnetic test strip, classified in class 422, subclass 57.
- II. Claims 1 and 6, drawn to a plurality of test strips, comprising magnetic test strips and less-magnetic test strips, classified in class 422, subclass 57.
- III. Claims 1, 6-8 and 16-20, drawn to a method for sorting test strips via a magnetic field, classified in class 209, subclass 214.
- IV. Claims 1 and 9-15, drawn to a method of making a magnetic test strip, classified in class 427, subclass 128.

Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because a test strip that lacks a magnetically attractive material has its own utility, such as measuring the pH level of a liquid. The test strip comprising a magnetically attractive material has separate utility such as a test strip for storing binary data.

Inventions (I and II) and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the test strips of Inventions I and II can be used for conducting measurements instead of being used for sorting.

Inventions (I and II) and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the magnetically attractive test strips of Inventions I, II and III can be made by applying a magnetically attractive film onto the test strips instead of incorporating a magnetically attractive material into the test strips.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). Invention III is directed towards a method for using test strips while Invention IV is directed towards a method for making test strips. The two inventions cannot be used together and they have different modes of operation.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

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During a telephone conversation with Jamie Greene on 4/19/06 a provisional election was made with preservation of traverse to prosecute the invention of Group III, claims 1, 6-8 and 16-20. Affirmation of this election must be made by Applicant in replying to this Office action. Claims 2-5 and 9-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

Claim 16 is objected to because of the following informalities:

It is suggested that the phrase "the one or more test strips" recited in line 3 of the claim be rephrased to "each of the one or more test strips".

Claim 18 is objected to because of the following informalities:

It is suggested that the phrase "the test strips are" recited in line 1 of the claim be rephrased to "each test strip is".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is dependent on itself. It appears that Applicant intended the claim to be dependent on claim 18. For examination purposes, the claim will be interpreted to be dependent on claim 18.

Claim 20 recites a method comprising the step of depositing test strips "into a container". The method comprises a second step of "monitoring changes in the gross weight of the container as the strips exit the container". It is not clear whether the claim is reciting two separate containers wherein the strips are transferred from one container to another or whether the claim intended to recite "monitoring changes in the gross weight of the container as the strips enter the container".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Rohr (US 5,445,971).

Rohr discloses a test kit comprising a reaction vessel with magnetically-attractable label disposed thereon for conducting binding assays (see lines 45-58, col. 2), wherein the reaction vessel can be a test strip (see line 17, col. 14). The labels are physically bound to the test strip in such manner that the test strip moves and adopts a specific spatial orientation when the test strip is exposed to a magnetic field (see lines 36-68, col. 19 and Fig. 4). The reference discloses that the movement of the test strip is variable and dependent on the amount of the magnetic labels that physically bind to the test strip (see lines 13-20, col. 18). The reference discloses a plurality of test strips that

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react differently under the influence of a magnetic field due to the different amounts of magnetic labels bound to them (see Figs. 2 and 6).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 16 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Hagen et al. (US 6,872,358 B2).

Hagen et al. disclose a test strip dispenser wherein the test strips to be dispensed are rectangular and flat (see lines 40-50, col. 5 and Fig. 2A). The reference discloses that in order to dispense a test strip, the dispenser utilizes a magnet to engage a magnet means that is disposed at an end or an edge of the test strip and moves the test strip away from the stack of test strips housed within the dispenser (see lines 1-23, col. 15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Rijckevorsel et al. (US 4,578,716) in view of Landsdorp et al. (US 5,514,340).

Van Rijckevorsel et al. disclose a test strip as well as a method for sorting out faulty test strips from the superior test strips during the manufacturing process. The reference discloses that faulty test strips can be sorted out from the superior test strips by marking them and manually removing them (see lines 17-20, col. 8). The reference does not disclose the use of a magnetic field to sort the test strips.

However, it is well-known in the art to sort articles of interest from a plurality of articles by labeling the articles of interest with magnetically attractive materials. Landsdorp et al. disclose a method for filtering out cells of interest from a large group of cells by labeling the cells of interest with a magnetic label and applying a magnetic field to the group of cells (see Abstract).

In light of the teachings of van Rijckevorsel et al. and Landsdorp et al., it would have been obvious to one of ordinary skill in the art to mark faulty test strips with magnetic labels and separate the faulty test strips from the superior test strips during the manufacturing process by means of a magnetic field so that the faulty test strips do not get packaged for sale.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hagen et al. in view of Caladine (GB 2 170 780 A).

As discussed above, the Hagen et al. reference discloses a method of applying a magnetic field to test strips having a magnetically attractive material disposed thereon to cause the test strips to move. However, the reference does not disclose a step of counting the test strips as they move in response to the magnetic field.

Caladine discloses a dispenser comprising a counter 41 that counts the number of times the dispenser has dispensed an article (see lines 30-38, page 1). The reference discloses that it is desirable to count the number of times a dispenser has dispensed an article for the purposes of detecting theft or malfunction (see lines 8-25, page 1).

In light of the teachings of Caladine, it would have been obvious to one of ordinary skill in the art to count each time the magnet of the dispenser disclosed by Hagen et al. engages the magnet means of a test strip so that theft or malfunction can be detected.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hagen et al. in view of Caladine as applied to claim 18 above, and further in view of Nambu (US 5,444,749).

Claim 18 is unpatentable over Hagen et al. in view of Caladine as discussed above. The Hagen et al. reference also discloses the step of moving test strips from inside a container to the outside of the container, but neither reference discloses that the counting is accomplished by monitoring the changes in the weight of the container as the test strips are dispensed.

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Nambu discloses an article dispensing system comprising a weight meter 9 that measures the weight of the articles dispensed into a container 8. The weight meter communicates with an operation unit 14 that calculates the number of articles dispensed based on the weight of articles dispensed and the weight of each individual article (see lines 4-13, col. 8).

In light of the teachings of Nambu, it would have been obvious to one of ordinary skill in the art to measure the number of test strips dispensed by the modified Hagen et al. dispenser by monitoring the changes in the weight of the dispenser in order to provide another means for counting the number of test strips dispensed by the dispenser.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PSH
4/19/06


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